COMPLETION INSTRUCTIONS
DAIDS EXPEDITED ADVERSE EVENT (EAE) FORM

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 1		Sent by	Enter the full name (first name and family name) of the individual to be contacted if the fax transmission is incomplete.	If a document scanner is available, the completed expedited adverse event reporting form and accompanying documentation may be scanned and sent to the DAIDS Safety Office via e-mail as an attachment.
Page 1		Phone	Enter the telephone number of the individual to be contacted if the fax transmission is incomplete.	
Page 1		Fax	Enter the fax number of the individual to be contacted if the fax transmission is incomplete.	
Page 1		E-mail	Enter the e-mail address of the individual to be contacted if the fax transmission is incomplete.	
Page 1		Date Sent	Enter the date the expedited adverse event reporting form is being sent to the DAIDS Safety Office as a 2-digit day, a 3-letter month, and a 4-digit year, e.g., 22/APR/2004.	
Page 1		No. of Pages	Enter the total number of pages being sent, including the expedited adverse event reporting form and any supporting documentation.	

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 1		Patient/Volunteer ID	Enter the Patient/Volunteer ID number of the subject who experienced the adverse event described in the expedited adverse event reporting form.	If the mother aborts, miscarries, or has a stillbirth, the event is reported as an adverse event for the mother. **For perinatal studies/trials**, if the infant is alive at birth and then dies, the event is reported as an adverse event for the infant.
Page 1	Reporter and Site Information	Site Name	Enter the name of the study/trial site.	
Page 1	Reporter and Site Information	Site Number	Enter the site number of the study/trial site.	**For non-network sites**, enter the site number assigned by the Regulatory Compliance Center (RCC) during protocol registration.
Page 1	Reporter and Site Information	Site Awareness Date	Enter the date the site first became aware of the adverse event occurring at a reportable level in the DD/MON/YYYY format.	If two distinct adverse events occur at the same time, report each event on a separate expedited adverse event reporting form.
Page 1	Reporter and Site Information	Site Report Date	Enter the date the expedited adverse event reporting form was completed in the DD/MON/YYYY format.	

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 1	Reporter and Site Information	Reporter Same as Sender?	If the individual at the site who is to be contacted for questions regarding the adverse event (the reporter) is the same as the individual who is sending the expedited adverse event reporting form, check YES and go on to the next section. If the individual at the site who is to be contacted for questions regarding the adverse event is <u>not</u> the same as the individual who is sending the expedited adverse event reporting form, check NO, continue in this section, and provide contact information for the Reporter.	
Page 1	Reporter and Site Information	Reporter Name	Enter the full name (first name and family name) of the individual at the site to be contacted for questions regarding the adverse event.	
Page 1	Reporter and Site Information	Phone	Enter the telephone number of the individual to be contacted for questions regarding the adverse event.	
Page 1	Reporter and Site Information	Fax	Enter the fax number of the individual to be contacted for questions regarding the adverse event.	
Page 1	Reporter and Site Information	E-mail	Enter the e-mail address of the individual to be contacted for questions regarding the adverse event.	

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 1	Report	New Report	Check this box if a New Report is being submitted.	A New Report is submitted when an adverse event is reported to the DAIDS Safety Office on an expedited basis for the first time. OR When an ongoing adverse event increases in severity to a higher grade than previously reported. OR When an adverse event that has been previously reported fully resolves and then re-occurs at a level requiring expedited reporting.
Page 1	Report	Follow-up Report	Check this box if a Follow-up Report is being submitted.	A Follow-up Report is submitted to provide additional information on a previously reported adverse event when additional information becomes available.
Page 1	Report	Date of Original Report	**For Follow-up Reports**, enter the original Site Report Date in the DD/MON/YYYY format.	If this is a New Report, leave the date field blank.

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 1	Report	Pages	**For Follow-up Reports**, check the box(es) that match the numbers(s) of each page of the expedited adverse event reporting form that contains follow-up information regarding the originally reported adverse event. Submit only the updated pages with follow-up information.	If follow-up information is entered on every page of the form, check the ALL box rather than checking boxes 1-7. If follow-up information is provided on a Supplemental DAIDS Expedited Adverse Event (EAE) Form, go to Section 12 of the expedited adverse event reporting form, check Other, and enter "Supplemental EAE Form" in the space provided. Be sure to include the Supplemental DAIDS EAE Form in the Follow-up Report submission.
Page 2	Header	Patient/Volunteer ID Number	Enter the Patient/Volunteer ID number of the subject.	If the mother aborts, miscarries, or has a stillbirth, the event is reported as an adverse event for the mother. **For perinatal studies/trials**, if the infant is alive at birth and then dies, the event is reported as an adverse event for the infant.
Page 2	Header	Site Report Date	Enter the date the expedited adverse event reporting form was completed in the DD/MON/YYYY format.	
Page 2		Is this a Serious Adverse Event (SAE) as defined in ICH E6?	If the adverse event described in the expedited adverse event reporting form meets any of the criteria listed in this section, check YES. Otherwise, check NO.	Please note that checking NO does not mean the adverse event does not need expedited reporting. Follow expedited reporting requirements as listed in the protocol.

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 2	1. Protocol Information	Protocol Number	Enter the Protocol Number of each DAIDS-sponsored study/trial in which the subject was enrolled at the time the adverse event occurred. Space is provided for three Protocol Numbers. If the blocks for the second and/or third protocol number are not needed (e.g., subject is enrolled in only one DAIDS-sponsored study/trial), check the N/A box as appropriate.	**For non-network sites**, enter the protocol number assigned by the RCC during protocol registration. In the event the subject is co-enrolled in more than three protocols, use additional page(s) as needed.
Page 2	1	Network Affiliation	For each Protocol Number provided, place a checkmark in the box next to the corresponding DAIDS study/trial network. Check only one box.	If there is no Network affiliation for the protocol, check None. If the Network affiliation is not listed, check Other Network and then enter the name of the Network in the space provided.
Page 2	2. Subject Information	Age	Enter the subject's age on the line provided and place a checkmark in the appropriate box to indicate whether the age is listed as Days, Months, or Years. Check only one box.	If the subject is less than 1 month old, enter age in terms of **Days**. If the subject is older than 1 month but less than 3 years of age, enter age in terms of **Months**. If the subject is older than 3 years of age, enter age in terms of **Years**.
Page 2	2	Sex at Birth	Place a checkmark in the appropriate box to indicate the subject's sex at birth. Check only one box.	
Page 2	2	Pregnant	Place a checkmark next to the box that indicates the pregnancy status of the subject. Check only one box. If the subject is pregnant, enter the duration of the pregnancy in weeks in the space provided.	

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 2	2	Height	**For pediatric studies/trials,** enter the subject's height on the line provided and place a checkmark in the appropriate box to indicate whether the height is listed as centimeters or inches.	
Page 2	2	Weight	Enter the subject's weight on the line provided and place a checkmark in the appropriate box to indicate whether the weight is listed as kilograms or pounds.	
Page 2	2	Race	Place a checkmark next to the box that indicates the race of the subject. Check only one box.	If the race is Black African, check Black or African American. If the race is Colored, check Other and enter Colored in the space provided. If the race of the subject does not match any of the options and the race is known, check "Other, specify" and record the race in the space provided.
Page 3	Header	Patient/Volunteer ID Number	Enter the Patient/Volunteer ID number of the subject.	Refer to instructions for Page 2 Header.
Page 3	Header	Report Date	Enter the date the expedited adverse event reporting was completed in the DD/MON/YYYY format.	
Page 3	3. For All Study Agents		Only if the study agent(s) is administered on a cyclic schedule, check the box provided and also complete the Supplemental DAIDS EAE Report Form.	Use additional page(s) as needed. If it is determined that the adverse event is not related to a study agent, but could be associated with study participation or procedure, do not complete this section.
Page 3	3.	A. Protocol Number	Using a column for each protocol, enter the appropriate protocol number(s) in the space(s) provided.	**For non-network sites**, enter the protocol number assigned by the RCC during protocol registration.

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 3	3	B. Generic/INN Name or the Study Agent Name/Abbreviation as listed in the Protocol	Using a column for each study agent, list the Generic/INN (International Non-proprietary Name) name OR the study agent name/abbreviation (as listed in the protocol) of each study agent administered to the subject.	**For combination study agents**, list the individual components by Generic/INN names OR list the protocol name abbreviation for the combination agent. **For blinded placebo controlled studies/trials,** the entry format is [study agent name/placebo], e.g., zidovudine/placebo.
Page 3	3	C. Dose	In the column for each study agent, enter the dose of each study agent administered to the subject prior to the onset of the adverse event.	
Page 3	3	D. Route	In the column for each study agent, enter the route of administration for each study agent administered to the subject.	
Page 3	4. For Study Agents Other Than Vaccines or Therapeutic Vaccines		If the study agent(s) is a vaccine or a therapeutic vaccine, check N/A and go on to Section 5.	Use additional page(s) as needed. If it is determined that the adverse event is not related to a study agent, but could be associated with study participation or procedure, do not complete this section.
Page 3	4	A. Schedule of Administration	In the column for each study agent, enter the schedule of administration for each study agent administered to the subject as the number of units (e.g., mg/mU) and frequency.	
Page 3	4	B. Date of First Dose	In the column for each study agent, enter the date that the subject took the first dose in the DD/MON/YYYY format.	

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 3	4	C. Date of Last Dose	In the column for each study agent, enter the last date that the subject took the study agent prior to the onset of the adverse event in the DD/MON/YYYY format.	
Page 3	4	D. Action Taken with Study Agent	In the column for each study agent, use the codes listed in the section row above to enter the study physician's action taken with the study agent after awareness of the adverse event.	If the subject died while still receiving the study agent, code D should be used. If code U is used, provide a further explanation in the Narrative Case Summary of the expedited adverse event reporting form (see Section 11).
Page 3	4	E. Date of Action Taken with Study Agent	In the column for each study agent, enter the date of the study physician's action taken with study agent listed in row D in the DD/MON/YYYY format.	If code O is used in row D, enter N/A in the date field. If the date of the action taken with study agent is unknown, enter UNK in the date field.
Page 3	4	F. Distributed by DAIDS	In the column for each study agent, if the study agent was obtained from DAIDS, check Yes. If the study agent was obtained by some other means (e.g., by the site), even if the study agent was required by the protocol, check No.	
Page 3	4	F. If No, specify manufacturer. If unknown, specify distributor	**If the study agent was not distributed by DAIDS**, in the column for each study agent, enter the name of the study agent manufacturer, if possible. If the manufacturer is unknown, enter the name of the study agent distributor.	If the manufacturer and distributor are unknown, enter UNK in the space provided.
Page 4	Header	Patient/Volunteer ID Number	Enter the Patient/Volunteer ID number of the subject.	Refer to instructions for Page 2 Header.

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 4	Header	Report Date	Enter the date the expedited adverse event reporting form was completed in the DD/MON/YYYY format.	
Page 4	5. For Vaccines Only (Including Therapeutic Vaccines)		If the study agent(s) is other than a vaccine or therapeutic vaccine, check N/A and go on to Section 6.	Use additional page(s) as needed. If it is determined that the adverse event is not related to a study agent, but could be associated with study participation or procedure, do not complete this section.
Page 4	5	a. – f.	List the date(s) of administration (in order of a., b., c., etc.) that corresponds with the vaccine(s) given in the DD/MON/YYYY format.	
Page 4		Action Taken with Study Agent	In the space provided, use the codes listed in the section row above to enter the study physician's action taken with the study agent to indicate how the entire vaccine regimen was managed after awareness of the adverse event.	If the subject died while still receiving the study agent, code D should be used. If code U is used, provide a further explanation in the Narrative Case Summary of the expedited adverse event reporting form (see Section 11).
Page 5	Header	Patient/Volunteer ID Number	Enter the Patient/Volunteer ID number of the subject.	Refer to instructions for Page 2 Header.
Page 5	Header	Report Date	Enter the date the expedited adverse event reporting form was completed in the DD/MON/YYYY format.	

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 5	6. Primary Adverse Event	Primary AE	List only one Primary AE. Choose the one term that best describes the nature of the adverse event being reported.	Accepted medical abbreviations may be used when describing the Primary AE. If a laboratory value is listed as the Primary AE, include the units of measure and specify which units are used, i.e., conventional or standard international (SI). Adverse events can be complex and often result in more than one abnormal sign, symptom, or laboratory parameter. Whenever possible, report the resulting overall diagnosis as the Primary AE. For example, report "pancreatitis" instead of "abdominal pain" or "Grade 4 amylase" or "Grade 3 nausea."

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 5	6	Relationship to Study Agent(s) Listed in Section 3	In the column for each study agent, enter the numeric code from the relationship code key below the table that reflects the study physician's assessment of relationship between the Primary AE and the study agent(s).	The term "pending" can only be used as a temporary assessment in the event of a death. Within the next 3 business days the study physician should make an assessment of relationship to study agent, to the best of his/her ability, and submit a Follow-up Report. (If no further assessment is made, the DAIDS Safety Office will change the assessment to "possibly related" after 3 business days from receipt of the original report.) If at any time, information becomes available that changes the assessment of relationship, a Follow-Up Report must be submitted. If it is determined that the adverse event is not related to a study agent, but could be associated with study participation or procedure, do not complete the "relationship to study agent" portion of this section.
Page 5	6	Severity Grade of Primary AE	Using the DAIDS toxicity table specified by the protocol, indicate the severity of the Primary AE.	
Page 5	6	Onset Date	Enter the date that the Primary AE first occurred at the level requiring reporting in the DD/MON/YYYY format.	If the Primary AE is a laboratory result, enter the date the specimen was obtained.
Page 5	6	Status Code	Using the status code key below the table, enter the status code of the subject at the most recent observation.	If code U is used, provide a further explanation in the Narrative Case Summary of the expedited adverse event reporting form (see Section 11).

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 5	6	Status Date	Enter the date of the most recent observation of the subject in the DD/MON/YYYY format.	
Page 5	7. Other Clinically Significant Events Associated with Primary AE	Other Clinically Significant Events Associated with Primary AE	List other clinically significant signs and symptoms that more fully describe the nature, severity, and/or complications of the Primary AE. If there are no other clinically significant signs and symptoms associated with the Primary AE, check None.	Use additional page(s) as needed. Clinical findings commonly associated with a diagnosis that do not provide additional detail about the nature, severity, or complications of the Primary AE can be included in the narrative but should not be reported in this section. For example, the presence or absence of chest pain, nausea + vomiting, or diaphoresis does not provide additional useful information to a diagnosis of acute myocardial infarction. However, significant events describing the severity or complications of the Primary AE such as a myocardial infarction complicated by cardiogenic shock or congestive heart failure should be reported in this section. Other reportable events that are not clearly associated with the Primary AE should be reported on another expedited report form as a distinct event.
Page 5	7	Severity Grade	Using the DAIDS toxicity table specified in the protocol, indicate the severity of each clinically significant sign or symptom listed.	
Page 5	7	Onset Date	Enter the date that each clinically significant sign or symptom listed first occurred at the level requiring reporting in the DD/MON/YYYY format.	

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 6	Header	Patient/Volunteer ID Number	Enter the Patient/Volunteer ID number of the subject.	Refer to instructions for Page 2 Header.
Page 6	Header	Report Date	Enter the date the expedited adverse event reporting form was completed in the DD/MON/YYYY format.	
Page 6	8. Relevant Laboratory Tests	Test	List relevant laboratory tests that help explain the nature, severity, and/or complications of the Primary AE and its relationship to the study agent(s). If there are no relevant laboratory tests, check None.	Use additional page(s) as needed. Do **not** convert units (e.g., from SI units to conventional units). Report results in units as provided by the laboratory performing the test. Copies of laboratory reports may be attached to the expedited adverse event reporting form, along with the normal ranges for each laboratory. If attaching copies of laboratory reports, enter "See Attached Laboratory Report(s)" in the space provided. (There is no need to complete this section if all laboratory reports are attached.) Remove subject identifiers from source documents and attach a PID (patient ID) label or write the PID on the laboratory reports.
Page 6	8	Collection Date	For each listed test, enter the date the laboratory specimen was obtained (not reported) in the DD/MON/YYYY format.	
Page 6	8	Result	For each listed test, enter the laboratory value.	
Page 6	8	Units	For each listed test, enter the units of measure and specify which units are used, i.e., conventional or standard international (SI).	
Page 6	8	Lab Normal Range	For each listed test, enter the laboratory normal range, including the units of measure, and specify which units are used, i.e., conventional or standard international (SI).	
Page 6	8	Lab Value Previous to this AE	For each listed test, enter the most recent previous laboratory value obtained prior to the onset of the adverse event. If unknown, enter UNK in the Previous Lab Value field.	

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 6	8	Previous Lab Collection Date	For each listed previous laboratory test, enter the date the most recent previous specimen was obtained (not reported) in the DD/MON/YYYY format, if known. If unknown, enter UNK in the date field.	
Page 6	9. Relevant Diagnostic Tests	Test	List non-laboratory diagnostic tests that help explain the nature, severity, and/or complications of the Primary AE and its relationship to the study agent(s). If there are no relevant diagnostic tests, check None.	Use additional page(s) as needed. Copies of diagnostic test results may be attached to the expedited adverse event reporting form. If attaching copies of diagnostic test results, enter "See Attached Diagnostic Test Results" in the space provided. (There is no need to complete this section if all diagnostic test results are attached.) Remove subject identifiers from source documents and attach a PID label or write the PID on the copies.
Page 6	9	Test Date	For each listed test, enter the date the diagnostic test was performed in the DD/MON/YYYY format.	
Page 6	9	Results/Comments	For each listed test, briefly state the results.	

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 6	10. Con-comitant Medications	Concomitant Medication	Other than the study agent(s) listed in Section 3, list all medications the subject was taking at the onset of the adverse event, including medications taken in the recent past if these medications are deemed relevant by the study clinician. Do not include medications used to treat the adverse event. If there are no concomitant medications, check None.	Use additional page(s) as needed. List the Generic/INN (International Non-proprietary Name) name wherever possible. **For combination medications**, list the individual components. However, if a medication is approved by the US FDA, then only list the medication brand name. Concomitant medications include pharmaceuticals, herbal preparations, alternative medications, and substances of abuse. Copies of medication lists may be attached to the expedited adverse event reporting form. If attaching copies of medication lists, enter "See Attached Medication List(s)" in the space provided. (There is no need to complete this section if all medication lists are attached.) Remove subject identifiers from source documents and attach a PID label or write the PID on the copy.
Page 6	10	Approximate Duration of Use	For each listed concomitant medication, enter the approximate length of time the subject was taking the medication, and indicate whether the length of time is listed as weeks, months, or years. If the length of time is unknown, enter UNK in the duration field.	
Page 7	Header	Patient/Volunteer ID Number	Enter the Patient/Volunteer ID number of the subject.	Refer to instructions for Page 2 Header.
Page 7	Header	Report Date	Enter the date the expedited adverse event reporting form was completed in the DD/MON/YYYY format.	

Page	Section	Field	Form Instructions	Special Instructions as Needed
Page 7	11. Narrative Case Summary	Narrative Case Summary	Provide a brief summary of the reported Primary AE, including all relevant information and details surrounding the adverse event.	Use additional page(s) as needed. Note that the DAIDS Safety Office does not receive copies of the Case Report Forms and thus has no other information on the subject.
Page 7	12. Additional Information	Additional Information	If attaching additional information, check the box next to each type of document attached. Check all that apply. If no documents are attached, check None.	If additional information is attached that is not listed, check Other and then identify the type of information in the space provided. If the Supplemental EAE Form is used, check Other and enter "Supplemental EAE Form" in the space provided.
Page 7	Certifier Information	Study Physician Signature	The study physician who has reviewed and verified the data on the expedited adverse event reporting form for accuracy and completeness must sign here.	The study physician who signs this section must be listed on the Form FDA 1572 or the DAIDS Investigator of Record Agreement. If the study physician is not available to sign the expedited adverse event reporting form, please submit this report within the required time period without the signature. The signature page must be re-submitted to the DAIDS Safety Office within the next 3 business days once the study physician has signed the expedited adverse event reporting form.
Page 7	Certifier Information	Study Physician Name Printed	Print legibly the name of the study physician who signed the expedited adverse event reporting form.	
Page 7	Certifier Information	Date	Enter the date the expedited adverse event reporting form was signed in the DD/MON/YYYY format.	

Page	Section	Field	Form Instructions	Special Instructions as Needed
Supple-mental EAE Form	Supple-mental EAE Form		Complete this form only if the study agent(s) listed in Section 3 is a therapeutic study agent(s) administered on a cyclic schedule.	For multiple study agents on a cyclic schedule, use one Supplemental EAE Form for each study agent.
Supple-mental EAE Form	Header	Patient/Volunteer ID Number	Enter the Patient/Volunteer ID number of the subject.	Refer to instructions for Page 2 Header.
Supple-mental EAE Form	Header	Report Date	Enter the date the expedited adverse event reporting form was completed in the DD/MON/YYYY format.	
Supple-mental EAE Form		Study Agent Name	In the space provided, list the Generic/INN (International Non-proprietary Name) name OR the study agent name/abbreviation (as listed in the protocol) of the study agent administered to the subject on a cyclic schedule.	
Supple-mental EAE Form	1. If event occurred during a dosing cycle		If the event did not occur during a dosing cycle, check the box for N/A and go directly to Question 2.	
Supple-mental EAE Form	1	a. Highest dose in this cycle	In the space provided, enter the highest dose given to the subject during the current cycle prior to the onset of the adverse event.	
Supple-mental EAE Form	1	b. Dose at time of AE onset	In the space provided, enter the last dose during the current cycle given to the subject prior to the onset of the adverse event.	

Page	Section	Field	Form Instructions	Special Instructions as Needed
Supple-mental EAE Form	1	c. Date this cycle started	Enter the date this cycle started in the DD/MON/YYYY format.	
Supple-mental EAE Form	1	d. Date previous cycle started	Enter the date the most recently completed previous cycle was started in the DD/MON/YYYY format.	
Supple-mental EAE Form	1	e. Number of previous cycles	Enter the total number of previously completed cycles as a 3-digit number.	Lead with one zero (0) if the number is between 10 and 99. Lead with two zeros (0) if the number is less than 10.
Supple-mental EAE Form	2. If event did not occur during a dosing cycle		If the event occurred during a dosing cycle, check the box for N/A and be sure to complete Question 1.	
Supple-mental EAE Form	2	a. Highest dose in previous cycle	In the space provided, enter the highest dose given to the subject in the most recent previous cycle completed prior to the onset of the adverse event.	
Supple-mental EAE Form	2	b. Last dose in previous cycle	In the space provided, enter the last dose given to the subject in the most recent previous cycle completed prior to the onset of the adverse event.	
Supple-mental EAE Form	2	c. Date previous cycle started	Enter the date the most recently completed previous cycle was started in the DD/MON/YYYY format.	

Page	Section	Field	Form Instructions	Special Instructions as Needed
Supple-mental EAE Form	2	d. Number of previous cycles	Enter the total number of previously completed cycles as a 3-digit number.	Lead with one zero (0) if the number is between 10 and 99. Lead with two zeros (0) if the number is less than 10.
Supple-mental EAE Form	Footer	Page Number	Enter the page number in the footer of each Supplemental EAE Form page submitted.	Number the first Supplemental EAE Form as Page 1, the second as Page 2, etc.